

## **REMARKS**

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

### **Summary of Telephone Interview**

Applicants wish to thank Examiner Chen for discussing the above-identified application with Applicants' representative on December 13, 2010. (Applicants note that although the interview was scheduled with both Examiner Chen and her Supervisor, the Supervisor was unexpectedly unable to attend.)

During the interview, Applicants set forth arguments based upon the previously filed responses. However, the Examiner took the general position that the recited components are all known in the art, and thus, the combination of these components is obvious. Applicants also discussed the previously provided experiments, and argued that these experiments demonstrate the unexpectedly superior results achieved by Applicants' composition. However, the Examiner disagreed, and indicated that the results are not unexpected.

The Examiner suggested that Applicants submit the arguments set forth during the interview, and submit claims with a narrower scope, such as claims directed to the particular compositions employed in the experiments and the specification. The Examiner indicated that she would look more favorably on claims with a narrower scope.

Applicants proposed amending independent claim 8 to incorporate at least one additive.

In accordance with the Examiner's suggestions, Applicants submit new and amended claims with varying scope, for the Examiner's careful consideration. Additionally, Applicants present detailed remarks regarding the patentability of the present claims.

**Due to the lengthy prosecution of this application, the Examiner is kindly requested to contact Applicants' representative prior to issuing another Office Action, to discuss any outstanding issues.** Applicants thank the Examiner in advance for her assistance in this regard.

### **Claim Amendments**

Claims 8, 10, 12 have been amended to incorporate at least one pharmaceutically acceptable additive, in accordance with page 7, lines 15-19 of the original specification.

Claim 10 has been amended to make editorial changes.

Claim 11 has been amended to depend from claim 8, rather than claim 10.

New claims 13-27 have been added to the application.

New claims 13-26 are based upon the particular ranges and compositions set forth on pages 6-7 of the specification, and Examples 1-4 provided in Table 1-1 on page 16 of the original specification.

New claim 27 recites the particular sweetening agents which are provided for on page 7, lines 25-27 of the original specification.

**Comments Regarding the Patentability of the Present Claims**

As recommended by the Examiner during the personal interview, Applicants have presented new claims of varying scope for the Examiner's consideration, based upon the particular ranges and compositions provided in the specification. Applicants respectfully assert that the patentability of the subject matter set forth in the present claims is supported by the arguments and evidence previously provided, as well as the comments provided below.

During the interview, the Examiner asserted that since each of the recited components has been known in the art, it would be obvious to combine the components to achieve the claimed compositions. However, Applicants respectfully disagree with this general position, as one of ordinary skill in the art would not arrive at the present invention by merely combining known components. Further, **any** combination of known components would not achieve the unexpected results of Applicants' invention, i.e., decreased syneresis and increased gel strength. Rather, in order to arrive at the unexpected results of the present invention, one of ordinary skill in the art must: choose a Chinese herbal medicine, choose to create a jelly form of the medicine, choose the particular components to be included in the jelly base, as well as the particular amount of said components, and choose to exclude many known components. (Applicants wish to remind the Examiner that the present claims include "consisting of" language, and directly exclude the presence of phosphate buffer and agar.)

Applicants kindly assert that one of ordinary skill in the art would not have arrived at the present invention from the disclosures of the cited references, absent the use of impermissible hindsight. Furthermore, the previously provided evidence supports the assertion that merely

combining components which are known in the art would not lead one to the present invention, or the unexpected results achieved therefrom. Rather, one of ordinary skill in the art would need to make many specific choices, (such as the particular components to include and exclude, as mentioned above), which are neither taught nor suggested by the prior art.

For example, in Mr. Fukuchi's Declaration submitted December 28, 2007, it was demonstrated that the presence of agar (which is a known component in jelly compositions) prevented the compositions of the Fukui reference from achieving the unexpected advantages of Applicants' composition. Specifically, as shown in Table 3 of the Declaration, the Sample in accordance with Applicants' invention had far less syneresis (0.17 % +/- 0.08) after 67 days than the samples according to the Fukui reference (37.86 % +/- 7.33, 31.37 % +/- 5.88, and 29.03 % +/- 2.75). Although the Fukui reference is no longer being relied upon by the Examiner, Applicants assert that this comparative data demonstrates that one of ordinary skill in the art would not arrive at the present invention by merely combining components which are known in the art, as such known components may negate the advantages of Applicants' invention.

Furthermore, in Mr. Fukuchi's Declaration submitted April 16, 2007, it was demonstrated that the three particular components recited in Applicants' claims, i.e., carrageenan, xanthan gum and locust bean gum, are necessary to achieve the unexpected and superior advantages of the present invention, as described below. Thus, combinations which incorporate one or two of the recited components would not achieve the advantageous results.

Specifically, in Comparative experiment A, a composition comprising Sho-saiko-to and carrageenan is unexpectedly inferior to a composition comprising Sho-saiko-to, carrageenan, carob bean gum and xanthan gum in terms of syneresis.

In Comparative experiment B, a composition comprising Kakkon-to, carrageenan and carob bean gum is unexpectedly far inferior to a composition comprising Kakkon-to, carrageenan, carob bean gum and xanthan gum in terms of syneresis.

In Comparative experiment C, compositions comprising Kakkon-to, carrageenan and carob bean gum or Kakkon-to and carrageenan are unexpectedly inferior to a composition comprising Kakkon-to, carrageenan, locust bean gum and xanthan gum in terms of syneresis.

Applicants assert that these showings of unexpected results demonstrate the patentability of the previously provided claims, as well as the newly added claims of varying scope.

The effects achieved by adding particular additives to pharmaceutical compositions depend upon the particular kind of composition and the particular kind of additive. Thus, the question to be considered in the present situation is whether one of ordinary skill in the art, when presented with the disclosures of the cited references, would have been motivated to make a composition comprising the particular components required by Applicants' claims, in the particularly required amounts, and excluding the components not present in Applicants' compositions. The fact that each recited component is not novel does not prohibit the particular combination from being novel and unobvious.

The Examiner relies upon *four* references in the obviousness rejection. The Nagasaka reference merely teaches Chinese herbal medicines, but fails to teach the base composition which is essential to Applicants' invention. Similarly, the Fujimaki reference merely demonstrates that Chinese herbal medicines are known in the art.

The Examiner relies upon the Ninomiya reference as teaching a jellied composition comprising carrageenan and locust bean gum. As discussed in the previous response, the Ninomiya reference relates to a jellied medical composition for oral administration, specifically to a jellied medical composition for oral administration that can easily be taken by patients of advanced age or patients with dysphagia. The Chinese medicines (Kakkon-to and Sho-saiko-to) are not disclosed in this reference.

A base of jelly in the reference contains carrageenan and locust (carob) bean gum, and *preferably further contains polyacrylic acid or a partly neutralized product or a salt thereof*. Applicants again remind the Examiner that the present claims include "consisting of" language, which excludes the additional components of the reference compositions. (MPEP 2111.03) The reference discloses a base used in a jellied medical composition for oral administration of one or more components selected from gelatin, pectin, xanthan gum, carrageenan, locust bean gum, mannan, etc., *more preferably a base containing carrageenan and locust bean gum*. In the examples, only a combination of κ-carrageenan and locust bean gum is used. This disclosure clearly fails to remedy the deficiencies of the Nagasaka and Fujimaki references, as it fails to motivate one of ordinary skill in the art to create a jelly composition, *consisting of* the particular components of Applicants' claims, in the particularly recited amounts, and not including the additional components of the reference compositions, i.e., polyacrylic acid.

Furthermore, Comparative experiment B of the Declaration submitted April 16, 2007 (discussed above) demonstrates that when a combination of  $\kappa$ -carrageenan, carob bean gum and xanthan gum is used, the syneresis is drastically and unexpectedly improved, compared with a combination of only carrageenan and carob bean gum. Ninomiya clearly fails to recognize the advantages of Applicants' composition, because the latter inferior combination is *preferred* in the Ninomiya reference.

The Examiner relies upon the San-Ei Chem reference as allegedly teaching a "binder for pharmaceutical preparation with xanthan gum and locust bean (carob bean gum) or carrageenan at 5-10 part of mixture of xanthan gum and locust bean gum (1-10:1-10) of carrageenan (Abstract), which can be converted into 1-10 w/w% xanthan gum and locust bean gum" (see Office Action, page 4 lines 7-10). However, Applicants kindly assert that the Examiner's interpretation of the reference is inaccurate.

A reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention (MPEP 2141.02.VI.). As shown in the English translation, this reference relates to a binder for a medical formulation containing an aqueous gel *consisting of xanthan gum and locust bean gum, or* an aqueous gel *consisting of carrageenan* as a binder (see page 2, lines 10-12). Further, the reference teaches "When xanthan gum or locust bean gum is *singly used*, they do not form any gel even if they are made a hydrous state. Therefore xanthan gum and locust bean gum must be used in combination...Carrageenan can be singly used" (emphasis added) (see page 2, lines 13-18).

It is untenable to assert that these teachings would motivate one of ordinary skill in the art to combine the three particular components (carrageenan, locust bean gum and xanthan gum), in the particular amounts required by Applicants' claims. The reference does not disclose or suggest the combination of xanthan gum, locust bean gum *and* carrageenan, and does not provide any example thereof. Moreover, the reference teaches away from combining the three components, since it clearly teaches that carrageenan can form a gel when used alone.

On the contrary, Applicants have demonstrated (see Comparative experiments A and C, discussed above) that carrageenan alone fails to achieve the unexpectedly superior results when of Applicants' compositions.

Lastly, the Examiner is requested to carefully consider the new claims, which incorporate particular combinations of components which are not taught or suggested by the prior art.

For the reasons provided above, Applicants respectfully assert that the compositions of the present claims would not have been obvious to one of ordinary skill in the art at the time of the invention, based upon the teachings of the cited references. Withdrawal of the rejection is respectfully requested.

**Conclusion**

Therefore, in view of the foregoing amendments and remarks, it is submitted that the ground of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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